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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,682	08/27/2001	David E. Townsend	150026.464	4343

500 7590 03/15/2007

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EXAMINER	
FORD, ALLISON M	
ART UNIT	PAPER NUMBER
1651	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/940,682	TOWNSEND, DAVID E.	
	Examiner	Art Unit	
	Allison M. Ford	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *09 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5,7,10-16,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,7,10-12,25 and 26* is/are rejected.

7)☒ Claim(s) *13-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

Applicants Request for Continued Examination was received on 9 January 2007, and entered into the application file. In that response, claims 1 and 5 were amended; claims 2-4, 6, 8-9 and 17-24 were cancelled; and new claims 25 and 26 were added.

Priority

Acknowledgement is made of applicant's claim for priority to provisional application 60/228,956, filed 28 August 2000, priority under 119(e). This provisional application provides support for all claims; thus all claims are given the effective filing date of 28 August 2000.

Applicant's claim for the benefit as a CIP of prior-filed application US 08/484,593 (now US Patent 6,387,650) under 35 U.S.C. 120 is also acknowledged. However, this prior filed application does not provide support for the subject matter of current claim 7, which requires the conditionally detectable marker to comprise tetrazolium red. Therefore, only claims 1, 5, 10-16, 25 and 26 receive the benefit of the effective filing date of 7 June 1995.

Response to Arguments

All arguments have been fully considered, and will be addressed below, each as appropriate. Rejections/objections not repeated herein have been withdrawn.

With regards to the rejection of claim 1 and dependents thereof under 35 USC 112, first paragraph, as failing to provide written description sufficient to show that the inventors were in possession of the entire genus of 'conditionally detectable markers,' as claimed, it is noted applicants have amended the claims to narrow the scope of the claims to conditionally detectable markers which

undergo a color change when reacted upon by a viable microorganism, which is supported by the specification; thus the rejection is withdrawn.

With regards to the rejection of claim 1 and dependents thereof under 35 USC 112, second paragraph, as omitting essential elements, it is noted applicants have incorporated a limitation into the independent claim disclosing how the conditionally detectable marker is detected; thus the rejection is withdrawn.

With regards to the rejection of the claims under 35 USC 102(b), 102(e) and/or 35 USC 103(a) over Carr et al (US Patent 5,064,756), Manafi et al (J. Applied Bacteriology, 1990), and Tuompo et al (US Patent 5,420,017), it is noted the claims, as currently amended, now require the conditionally detectable marker and the substrate for an aminopeptidase to be separate molecules, which none of the cited references disclose; therefore the rejections of record are withdrawn. However, a new rejection under 35 USC 103(a) based on the cited references is made.

However, while the rejections under 35 USC 102 are withdrawn, in order to be clear and to hopefully advance prosecution, the examiner does wish to briefly address applicants' arguments:

It appears applicant are basing their traversal on the fact that the cited references do not utilize the disclosed compositions for **detection** of 'target' microorganisms, or that the aminopeptidase substrates included in the disclosed compositions **are** capable of being cleaved by what is considered the 'target' microorganisms of the prior art methods.

These arguments are not persuasive, because the current claims are directed to a composition, not to methods of using the composition [to detect microorganisms].

It is noted that in the cited prior art, the disclosed compositions comprise aminopeptidase substrates which are capable of being cleaved by aminopeptidases, said aminopeptidases are present in

what was being considered the 'target microorganisms'. However, while applicants argue this is in contradiction to the claim limitations, it is maintained that the claimed composition cannot be defined by its intended use. The compositions of the cited prior art contain the same aminopeptidase substrates as those currently claimed or taught in the specification (for example, 7-N-(alanyl)-7-amido-4-methylcoumarin), the fact that the prior art compositions were used in methods where they were exposed to 'target' microorganisms that did comprise aminopeptidases capable of cleaving the substrate, such does not change the fact that the disclosed composition is one and the same as that claimed.

A new use, new function or unknown property of a known product does not necessarily make the product patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). The aminopeptidase substrates within the scope of the current claims are not new (as evidenced by their disclosure in the cited prior art); rather, it appears the discovery that specific bacteria, namely *Salmonella, Listeria, E.coli* OH157, *Campylobacter, Staphylococcus aereus, Cryptosporidium*, or *Giardia*, do not contain an aminopeptidase capable of cleaving these specific substrates, and thus these substrates can be used to detect the presence or absence of these bacteria in a sample, is the discovery of the present invention. However, such is a method, not a composition.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 13, 25 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 currently lacks proper antecedent basis for the limitation "said bacteria" in the first line of the claim; due the amendment of claim 1, it appears claim 5 should now read, "said target microorganism". Examination has been conducted as such.

Applicant's claim 13 still stands rejected as being dependent upon a cancelled base claim (8); therefore the scope of claim 13 cannot be envisioned.

Applicants new claim 25 is directed to a composition for detecting *Campylobacter* in a sample, said composition comprising (i) a conditionally detectable marker that undergoes a color change when reacted upon by *Campylobacter*; and (ii) a substrate for an aminopeptidase, wherein said substrate comprises a signal moiety that provides a detectable signal when cleaved; and wherein the (i) conditionally detectable marker and (ii) the substrate for an aminopeptidase are not the same molecule.

It is not clear if the conditionally detectable maker only undergoes a color change when reacted upon by *Campylobacter*, or if it undergoes a color change when reacted upon by any viable microorganism in the sample.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 5, 7, 10-16 and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuompo et al (US Patent 5,420,017) and Manafi et al (J Appl Bacteriol, 1990).

Applicant claims 1 and 25 are directed to a composition for detecting a target microorganism, specifically *Campylobacter*, in a sample, the composition comprising (i) a conditionally detectable marker that undergoes a color change when reacted upon by a viable microorganism; and (ii) a substrate for an aminopeptidase, wherein said substrate comprises a signal moiety that provides a detectable signal when cleaved; and wherein the (i) conditionally detectable marker and (ii) the substrate for an aminopeptidase are not the same molecule. Claim 7 requires the conditionally detectable marker to be tetrazolium red. Claims 10 and 26 require the aminopeptidase to y be L-alanine aminopeptidase. Claims 11 and 12 require the substrate to be selected from the disclosed group, specifically L-alanin-7-amido-4-methylcoumarin.

Claims 5 and 13 are directed to the intended use of the composition (detection of specific microorganisms), these claims recite specific target microorganisms as well as the non-target microorganisms the composition is to detect.

With regards to claims 5 and 13, which are related to the intended use of the composition (detection of specific microorganisms), please note that in cases where the body of the claim fully and intrinsically sets forth all the limitations of the invention, such as all components of a composition, recitations that merely states the intended use of the composition, rather than any distinct definition of any of the claimed invention's limitations, are not considered limitations and are of no significance to claim construction. See MPEP § 2111.02. Therefore, claims 5 and 13 are given no patentable weight and have been included in the rejection of the claims directed to the composition.

Tuompo et al also disclose a method and kit for detecting Gram-negative microorganisms in a sample. The method relies on use of a composition comprising a chromogenic reagent in an amount effective to detect the Gram negative bacteria; preferably the chromogenic reagent is a tetrazolium salt, particularly triphenyltetrazolium chloride (tetrazolium red), which produces a color change from colorless

to red upon biochemical reduction by Gram-negative bacteria (See Tuompo et al, col. 2, ln 25-35 & claim 4).

Manafi et al also teach a method and composition for detecting the presence of Gram-negative bacteria in a sample; however the method of Manafi et al is capable of differentiating between Gram-negative and Gram-positive bacteria. The composition of Manafi et al comprises the conditionally detectable marker L-alanine-7-amido-4-methylcoumarin (AAMC), which produces a fluorescent color change when cleaved by the L-alanine-aminopeptidase found in the cell wall of Gram-negative bacteria (See Manafi et al, See pages 823-827).

Based on the disclosed compositions of Tuompo et al and Manafi et al, it would have been well within the purview of one of ordinary skill in the art, at the time the invention was made, to combine the two compositions of Tuompo et al and Manafi et al, each designed to detect Gram-negative bacteria in a sample, to create a single, superior test composition capable of detecting Gram-negative bacteria. It has been held that it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose (in the instant case: detecting the presence of Gram-negative bacteria), in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, the invention as a whole would have been prima facie case obvious to one of ordinary skill in the art at the time the invention was made.

Claim Objections

Claims 14-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison M. Ford whose telephone number is 571-272-2936. The examiner can normally be reached on 7:30-5 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leon B Lankford, Jr
Primary Examiner
Art Unit 1651